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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,954	07/21/2003	Richard Mihalik	506401-0058	4614
27910	7590	05/18/2004	EXAMINER	
STINSON MORRISON HECKER LLP ATTN: PATENT GROUP 1201 WALNUT STREET, SUITE 2800 KANSAS CITY, MO 64106-2150			PRYOR, ALTON NATHANIEL	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/623,954

**Applicant(s)**

MIHALIK, RICHARD

**Examiner**

Alton N. Pryor

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/21/03</u> . | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### ***Claim Rejection under 35 U.S.C. 112, 1st paragraph***

**I. The following is a quotation of the first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24,25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating parasite infection, does not reasonably provide enablement for preventing parasite infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make / use the invention commensurate in scope with these claims. The asserted utility is not believable on its face. It is not known how a method wherein a composition is claimed can be administered to prevent parasite infection. The state of the art is what prior art knows about the invention. There is no known art wherein a certain composition is administered to successfully prevent parasite infection. The level of ordinary skill in the art is high but only in the art of treating / controlling said infection. The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by the applicant. In the instant invention the predictability is very low and consequently, the

need for the higher levels of direction and guidance by the applicant. However, the amount of direction and guidance provided by the applicant is limited to treatment. There is no evidence in the specification that established correlation between the experiment and the claimed utility. The quantity of experimentation required to use the method as claimed in the instant invention, based on applicant's disclosure would be undue because, one of ordinary skill in the art would have performed significant amount of experiments.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10,12,13,16 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 59027819; 2/14/84). JP '819 teaches a milk chocolate composition comprising 15-60 % pyrantel pamoate. See abstract. In a claim to a composition, a statement regarding the intended use of the composition has no patentable significance.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP '819 on record as applied to claims 1-10,12,13,16. JP '819 teaches all that is recited in claim 11 except for the chocolate composition comprising 62% pyrantel pamoate. It would have been obvious to one having ordinary skill in the art to make the chocolate composition comprising 62% pyrantel pamoate. One having ordinary skill in the art would have been motivated to do this since JP '819 teaches a chocolate composition comprising 60% pyrantel pamoate which is not significantly different from 62%.

Claims 19,24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burger et al (ZA 9104494; 4/29/92). Burger teaches a method of administering to an animal (dog or cat or horses) a dosage (composition) comprising pyrantel pamoate in order to control tapeworms and roundworms. See abstract. Burger does not teach the instant amount of pyrantel being 17% or greater. It would have been obvious to one having ordinary skill in the art to determine the optimum amount of pyrantel pamoate to use. One would have been motivated to do this in order to find the most effective amount of pyrantel pamoate for controlling said worms. It is very possible that the optimum amount of pyrantel pamoate employed would have fallen within the broad range of 17% or greater.

### ***Double Patenting Rejections***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6596714. Although the conflicting claims are not identical, they are not patentably distinct from each other because USPN '714 teaches an invention comprising the administration of a composition (paste) comprising pyrantel pamoate to an animal (equine) to control parasites (Anoplocephala). Although USPN '714 does not state in the claims that the pyrantel pamoate concentration is greater than 17% (as instantly claimed), the specification of USPN '714 discloses that pyrantel pamoate can range from 17% to 65%. See USPN '714 column 3 lines 49-57, column 4 lines 14-67.

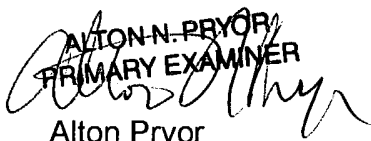
Claims 1-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6207179. Although the conflicting claims are not identical, they are not patentably distinct from each other because USPN '179 teaches an invention comprising the administration of a composition (paste) comprising pyrantel pamoate to an animal (equine) to control parasites (Anoplocephala). Although USPN '179 does not state in the claims that the pyrantel pamoate concentration is greater than 17% (as instantly claimed), the specification of USPN '179 discloses that pyrantel pamoate can range from 17% to 65%. See USPN '179 column 3 lines 46-54, column 4 lines 14-67.

***Telephonic Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 561\*272-0602. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 561-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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AU 1616